NeuroSense Investor Relations

NeuroSense Provides Business Update and Progress for the First Half of 2025

CAMBRIDGE, Mass., July 31, 2025 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a late-stage clinical biotechnology company developing novel treatments for severe neurodegenerative diseases, today provided business update with corporate highlights to date and financial results of the first half of 2025.

NeuroSense is advancing PrimeC, its investigational combination therapy for amyotrophic lateral sclerosis (ALS), through regulatory pathways while preparing for a pivotal Phase 3 trial.

"The first half of 2025 has been transformational for NeuroSense. We regained compliance with Nasdaq's stockholders' equity requirement, generated additional long–term data from our Phase 2b ALS, PARADIGM study, and advanced our manufacturing capabilities," said Alon Ben–Noon, Chief Executive Officer of NeuroSense. "Our team is focused on accelerating the path to a pivotal Phase 3 trial as the next step in potentially bringing a meaningful treatment to people living with ALS as quickly as possible."

Upcoming Corporate Highlights for H2 2025 include:

- **NOC/c Submission in Canada** – Following feedback from Health Canada that the Company's initial request did not fulfill the criteria for advanced consideration under the Notice of Compliance with conditions (NOC/c) policy, and in line with Health Canada's suggestion, NeuroSense plans to submit a new request supported by additional data, with the goal of securing an NOC/c for PrimeC.
- **Phase 3 trial commencement** – Following positive regulatory feedback from the FDA, NeuroSense plans to begin a multinational Phase 3 study of PrimeC in ALS in the second half of 2025.
- **Advancing binding term sheet with a global pharmaceutical partner** – Following the execution of a binding term sheet in the fourth quarter of 2024 to advance the development and commercialization of PrimeC, its proprietary treatment drug for ALS in certain key territories, discussions are continuing and may yield a definitive partnership agreement in the near future.

First Half 2025 Corporate Highlights

- **Nasdaq listing compliance restored**
  In January 2025 NeuroSense received formal notice from Nasdaq that it had regained compliance with the stockholders' equity requirement after completing a $5 million private placement in December 2024. The financing strengthened the Company's balance sheet and raised shareholders' equity above Nasdaq's minimum requirement.

- **Additional long–term data from the Phase 2b PARADIGM study**
  In February 2025 NeuroSense reported new analyses from the completed 18–month Phase 2b PARADIGM study in ALS. The new analysis revealed that in the per-protocol population (participants who adhered to the protocol), treatment with PrimeC slowed functional decline by ~40%. Overall survival improved by 74%, complication–free survival improved by 79%, and patients experienced slower decline in slow vital capacity by 26%. These data reinforce the disease–modifying potential of PrimeC and underpin the design of the planned Phase 3 study.

- **Presentation of biomarker and mechanistic data**
  At the Annual Meeting of the American Academy of Neurology (AAN) in April 2025, members of NeuroSense's scientific advisory board presented further analyses from the PARADIGM study. Dr. Jeremy Shefner highlighted safety, efficacy and biomarker data showing that PrimeC has disease–modifying potential and may redefine ALS treatment. Dr. Jeffrey Rosenfeld discussed microRNA modulation and iron–related biomarkers as evidence of multi–target engagement. These findings were later expanded upon in a release describing how PrimeC consistently modulated microRNAs associated with ALS, providing mechanistic insight consistent with observed clinical improvements.

- **Manufacturing scale–up to commercial levels**
  In May 2025 NeuroSense successfully scaled production of PrimeC to a commercial level and selected a global contract development and manufacturing organization (CDMO) to ensure supply chain readiness for potential commercialization. The Company validated the manufacturing process, qualified suppliers, and demonstrated product stability supporting a 36–month shelf–life.

H1 2025 Financial Results:

- **Research and development expenses** for the six months ended June 30, 2025 and 2024 were $2,503 thousand and $3,733 thousand, respectively. The decrease of $1,230 thousand, or 32.9%, was mainly attributed to the decrease in clinical activity.
- **General and administrative expenses** for the six months ended June 30, 2025 and 2024 were $2,189 thousand and $2,291 thousand, respectively. The decrease of $102 thousand, or 4.4%, is considered immaterial.
- **Operating expenses** for the six months ended June 30, 2025 and 2024 were $4.7 million and $6 million, respectively due to the reasons described above.

A summary of NeuroSense's unaudited consolidated financial results is included in the tables below.

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited balance sheets

U.S. dollars in thousands

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalent	**666**	3,378
Other receivables	**847**	989
Restricted deposit	**43**	35
Total current assets	**1,556**	4,402
Non-current assets:		
Property, plant and equipment, net	**63**	66
Operating right of use assets	**42**	84
Restricted deposit	**23**	23
Total non-current assets	**128**	173
Total assets	**1,684**	4,575
Liabilities and Equity		
Current liabilities:		
Trade payables	**1,093**	1,160
Other payables	**1,110**	832
Total current liabilities	**2,203**	1,992
Total liabilities	**2,203**	1,992
Shareholders' equity:		
Authorized: 90,000,000 shares at March 31, 2025 and December 31, 2024; Issued and outstanding: 24,602,405 and 23,228,941 shares at June 30, 2025 and December 31, 2024, respectively	**-**	-
Share premium and capital reserve	**40,850**	39,243
Accumulated deficit	**(41,369)**	(36,660)
Total Shareholders' equity (deficit)	**(519)**	2,583
Total liabilities and shareholders' equity (deficit)	**1,684**	4,575

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited Statements of Comprehensive Loss

U.S. dollars in thousands except share and per share data

	Six months ended June 30, 2025		Six months ended June 30, 2024
Research and development expenses	**(2,503)**	(*)	(3,733)
General and administrative expenses	**(2,189)**	(*)	(2,291)
Operating loss	**(4,692)**		(6,024)
Financing expenses, net	**(17)**		(237)
Net loss and comprehensive loss	**(4,709)**		(6,261)

Basic and diluted net loss per share	**(0.19)**	(0.37)
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	**25,402,649**	16,773,806

(*) Reclassified

NeuroSense Therapeutics Ltd.

Condensed Interim Unaudited Statements of Changes in Equity

U.S. dollars in thousands (except for share and per share data)

	Ordinary shares		Share premium and capital reserve	Accumulated deficit	Total equity
	Number	Amount			
Balance as of January 1, 2025	23,228,941	$ -	$ 39,243	$ (36,660)	$ 2,583
Issuance of shares, net	883,952	-	1,288	-	1,288
Exercise of options and vested RSUs	194,000		13		13
Share-based compensation	295,512		306		306
Net loss and comprehensive loss	-	-	-	(4,709)	(4,709)
Balance as of June 30, 2025	24,602,405	$ -	$ 40,850	$ (41,369)	$ (519)

About ALS

Amyotrophic lateral sclerosis ("ALS") is an incurable neurodegenerative disease that causes complete paralysis and death within 2-5 years from diagnosis. Every year, more than 5,000 people are diagnosed with ALS in the U.S. alone, with an annual disease burden of $1 billion. The number of people living with ALS is expected to grow by 24% by 2040 in the U.S. and EU.

About PARADIGM

PARADIGM is a prospective, multinational, randomized, double-blind, placebo-controlled Phase2b (NCT05357950) clinical trial of PrimeC in ALS. The trial included 68 participants living with ALS in Canada, Italy, and Israel.

During the first 6 months of the trial, 45 participants were randomized to receive PrimeC, and 23 participants were randomized to receive placebo. This was followed by a 12-month open-label extension with all participants receiving PrimeC in a blinded manner, where neither the participants nor the clinical staff were aware of the initial treatment allocation.
Most patients enrolled in both the active and placebo arms of the trial were concurrently treated with Riluzole, the ALS standard of care medication, indicating PrimeC slowed disease progression well beyond the level afforded by the FDA approved ALS drug.

About PrimeC

PrimeC, NeuroSense's lead drug candidate, is a novel extended-release oral formulation composed of a unique fixed-dose combination of two FDA-approved drugs: ciprofloxacin and celecoxib. PrimeC is designed to synergistically target several key mechanisms of ALS that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired ribonucleic acid ("RNA") regulation to potentially inhibit the progression of ALS. NeuroSense completed a Phase 2a clinical trial which met its safety and efficacy endpoints including reducing functional and respiratory deterioration and statistically significant changes in ALS-related biological markers indicating PrimeC's biological activity. PrimeC was granted Orphan Drug Designation by the U.S. Food and Drug Administration and the European Medicines Agency.

About NeuroSense

NeuroSense Therapeutics, Ltd. is a clinical-stage biotechnology company focused on discovering and developing treatments for patients suffering from debilitating neurodegenerative diseases. NeuroSense believes that these diseases, which include amyotrophic lateral sclerosis (ALS), Alzheimer's disease and Parkinson's disease, among others, represent one of the most significant unmet

medical needs of our time, with limited effective therapeutic options available for patients to date. Due to the complexity of neurodegenerative diseases and based on strong scientific research on a large panel of related biomarkers, NeuroSense's strategy is to develop combined therapies targeting multiple pathways associated with these diseases.

For additional information, we invite you to visit ourwebsite and follow us on LinkedIn, YouTube and X. Information that may be important to investors may be routinely posted on our website and these social media channels.

Forward-Looking Statements

This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on NeuroSense Therapeutics' current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict and include statements regarding a commercial launch in Canada and market potential. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. The future events and trends may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. These risks include the risk that that the commercial launch of PrimeC will not expeditious, that there will not be dependable and compliant sourcing for commercial-scale production volumes of PrimeC, that the shelf life of PrimeC will not be as anticipated, lower than anticipated market opportunity in Canada and elsewhere, that regulatory approvals for PrimeC will be delayed or not obtained in Canada or elsewhere; insufficient capital to complete development of PrimeC, the timing of expected regulatory and business milestones; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the uncertainty regarding outcomes and the timing of current and future clinical trials; the development and commercial potential of any product candidates of Neurosense; the ability of NeuroSense to remain listed on Nasdaq; and other risks and uncertainties set forth in NeuroSense's filings with the Securities and Exchange Commission (SEC). You should not rely on these statements as representing our views in the future. More information about the risks and uncertainties affecting NeuroSense is contained under the heading "Risk Factors" in the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 7, 2025 and NeuroSense's subsequent filings with the SEC. Forward-looking statements contained in this announcement are made as of this date, and NeuroSense undertakes no duty to update such information except as required under applicable law.

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Additional assets available online: Photos (1)

https://neurosense.investorroom.com/2025-08-01-NeuroSense-Provides-Business-Update-and-Progress-for-the-First-Half-of-2025